

### III. REMARKS/ARGUMENTS

#### A. Restriction Requirement

The Examiner has made a Restriction Requirement in the present Office Action, and has stated that the application must be restricted to one of the following inventions:

Group I: Claims 1-16 drawn to a method for managing a patient with Alzheimer's disease or at risk of developing Alzheimer's disease, classified in class 514, subclass 171 and 548 for example.

Group II: Claims 17-21 drawn to a kit for an assay of A $\beta$  serum concentration comprising specific components herein, classified in class 514, subclass 171 and 548 for example.

Group III: Claims 22-40 drawn to a method for treating, preventing, or inhibiting an APP processing disorder in a mammal, classified in class 514, subclass 171 and 548 for example.

#### ELECTION

In response to the restriction requirement, Applicant hereby, without traverse, elects Group I, Claims 1-16 drawn to a method for managing a patient with Alzheimer's disease or at risk of developing Alzheimer's disease. The claims have been amended without prejudice accordingly.

In response to the election of species requirement under 35 U.S.C. 121, Applicant hereby provisionally elects the following species with traverse:

**“lovastatin”** as the active ingredient.

It is respectfully submitted that all of the pending claims (claims 1-16) read on this active ingredient.

This election is made with traverse as the Examiner is requested to consider all of the subject matter of the pending claims and not simply the species which is elected. The Examiner's attention is respectfully directed to the Manual of Patent Examining Procedure, Eighth Edition, Incorporating Revision No. 1, § 803, a copy of which is attached, which states the following:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Applicant respectfully submits that the search and examination of the entire application can be made without serious burden, and therefore respectfully requests that the Examiner remove the election requirement as to the species and consider all of the subject matter of the pending claims.

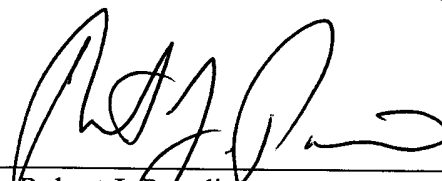
Applicant respectfully submits that the requirement for election of a species is particularly unduly restrictive to the applicant. However, this traversal is not to be construed as an admission by the applicant that the species are not patentably distinct. Applicant is respectfully traversing on the sole grounds that the search and examination of the species can be made without serious burden to the Examiner.

It is believed that no fee is due for this response. If it is determined that any fee is due, the Examiner is specifically authorized to charge said fee to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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## 802.01 Meaning of "Independent" and "Distinct"

35 U.S.C. 121 quoted in the preceding section states that the Commissioner may require restriction if two or more "independent and distinct" inventions are claimed in one application. In 37 CFR 1.141, the statement is made that two or more "independent and distinct inventions" may not be claimed in one application.

This raises the question of the subjects, as between which the Commissioner may require restriction. This, in turn, depends on the construction of the expression "independent and distinct" inventions. The "Independent" of course, means not dependent. If "distinct" means the same thing, then its use in the statute and in the rule is redundant. If "distinct" means something different, then the question arises as to what the difference in meaning between these two words may be. The hearings before the committees of Congress considering the codification of the patent laws indicate that 35 U.S.C. 121 enacts as law existing practice with respect to division; at the same time introducing a number of changes.

The report on the hearings does not mention as a change that is introduced, the subjects between which the Commissioner may properly require division.

The term "independent" as already pointed out, means not dependent. A large number of subjects between which, prior to the 1952 Act, division had been proper, are dependent subjects, such as, for example, combination and a subcombination thereof, as process and apparatus used in the practice of the process, as composition and the process in which the composition is used, as process and the product made by such process, etc. If section 121 of the 1952 Act were intended to direct the Commissioner never to approve division between dependent inventions, the word "independent" would clearly have been used alone. If the Commissioner has authority or discretion to restrict independent inventions only, then restriction would be improper as between dependent inventions, e.g., the examples used for purpose of illustration above. Such was clearly not the intent of Congress. Nothing in the language of the statute and nothing in the hearings of the committees indicate any intent to change the substantive law on this subject. On the contrary, joinder of the term "distinct" with the

term "independent", indicates lack of such intent. The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact, "distinct" inventions, even though dependent.

## INDEPENDENT

The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process.

## DISTINCT

The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art). It will be noted that in this definition the term related is used as an alternative for dependent in referring to subjects other than independent subjects.

It is further noted that the terms "independent" and "distinct" are used in decisions with varying meanings. All decisions should be read carefully to determine the meaning intended.

## 802.02 Definition of Restriction

Restriction, a generic term, includes the practice of requiring an election between distinct inventions, for example, election between combination and subcombination inventions, and the practice relating to an election between independent inventions, for example, and election of species.

## 803. Restriction - When Proper

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent

(MPEP § 806.04 - § 806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

### CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

### GUIDELINES

Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases.

Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement.

If there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. 103, restriction should not be required. *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).

For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows, by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria is set forth in MPEP § 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus-species, see MPEP § 806.04(a) - § 806.04(i) and § 808.01(a).

### 803.01 Review by Examiner with at Least Partial Signatory Authority

Since requirements for restriction under 35 U.S.C. 121 are discretionary with the Commissioner, it becomes very important that the practice under this section be carefully administered. Notwithstanding the fact that this section of the statute apparently protects the applicant against the dangers that previously might have resulted from compliance with an improper requirement for restriction, IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION. Therefore, to guard against this possibility, only an examiner with permanent or temporary full signatory authority may sign final and non-final Office actions containing a final requirement for restriction, except that an examiner with permanent or temporary partial signatory authority may sign non-final Office actions containing a final requirement for restriction.

### 803.02 Restriction — Markush Claims

#### PRACTICE RE MARKUSH-TYPE CLAIMS

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a